REMARKS

I. Status of the Claims

Claims 1, 3-7, 9, 11 and 13-20 are pending and stand rejected, variously, under 35 U.S.C. §112 (first and second paragraphs) and §103. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

Claims 15 is objected to as depending from a canceled claim. The claim has been canceled, rendering the rejection moot.

II. Rejections Under 35 U.S.C. §112

A. First Paragraph – "Treating"

Claims 1, 3-7, 9, 11, and 13-20 are rejected as lacking enablement for inhibiting infection. Applicants traverse.

First, the examiner argues that "inhibits" is synonymous with "prevents." Applicants do not agree. Inhibits means that an infection is somehow limited. While that might ***encompass*** prevention, inhibition could mean limiting of an existing infection or limiting of an impending infection, *i.e.*, treatment prior to exposure, wherein the infection is not prevented but is limited due to the existence of drug in the subject's system. For this reason alone, applicants believe the rejection is improper.

Furthermore, the examiner attempts to "support" this rejection by using very isolated comments from applicants' own specification, such as "there is no known method in the art for the prevention of HIV infection" and "a vaccine has not been approved for parainfluenza infection." HIV is not being claimed, and the absence of a vaccine for PIV is completely off the point. Applicants submit that the attached paper by Gower & Graham (2001) demonstrates benefit of administration prior to infection, thereby indicating that prevention of infection is

taking place (see FIGS. 2-4 for time points up to 3 days prior to infection). This article is far more relevant to the question of enablement for "prevention" than unwarranted extrapolations from other viral systems. In short, there is no meaningful evidence of record to support the rejection.

Reconsideration and withdrawal of the rejection is therefore respectfully requested.

B. First Paragraph – "HMG-CoA Reductase Inhibitors"

Claims 1, 3-7, 9, 11, and 14-20 are rejected as lacking enablement for use of HMG –CoA reductase inhibitors. Applicants traverse.

The entire rejection is premised on one argument – that "'an inhibitor of HMG-CoA reductase' is seen to be merely functional language." The only "support" for this rejection is a non-sensical citation to *Eli Lilly*, which dealt with written description, not enablement, and an equally as irrelevant citation to a 1938 Supreme Court case dealing with the alleged "point of novelty." Indeed, applicants are not claiming HMG-CoA reductase inhibitors are novel – it is their use in treating RSV infections that is novel ***and*** non-obvious.

The examiner is directed to the USPTO's website, where a search for the term "HMG-CoA reductase inhibitor" revealed some 131 patents using this language in their claims. Thus it ***cannot*** be that use of such "functional" language is *per se* improper. Thus, it is incumbent upon the examiner to explain why, in this particular instance, the term is improperly utilized. In the absence of such an explanation – ***and there is no explanation of record*** – this is an attempt by the examiner to improperly shift the burden to applicants to defend their presumptively enabling disclosure. *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971).

Reconsideration and withdrawal of the rejection is therefore respectfully requested.

C. First Paragraph – Combinations

Claims 15-17 are rejected as lacking enablement for use of combinations of HMG-CoA reductase inhibitors and a nucleoside analog or protease inhibitor or antibody composition. Applicants traverse, but have canceled claims 15 and 16. As to claim 17, applicants traverse.

The examiner's rejections devolves into two essential arguments. First, it is argued that there are no examples of combination treatments. Second, it is argued that drug combinations can potentially be toxic. However, neither of these arguments provides the basis for lack of enablement.

With regard to the lack of examples, it is will known that examples ***are not required to establish enablement***. Here, applicants readily acknowledge that an example showing a combination of an HMG-CoA reductase inhibitor with an anti-RSV antibody is not presented. However, it is quite false that the absence of such an example means that there insufficient information on "how to treat an infection by a RSV virus in a patient in need of such treatment." Indeed, one of skill in the art need simply refer to the literature provided on the use of anti-RSV antibodies – a well known therapy – and combine this with the teachings of the specification on the use of HMG-CoA reductase inhibitors and with Section V, addressing combination therapies. The examiner has cited no evidence in support of this rejection and, as such, has again improperly attempted to shift the burden to applicants to defend their presumptively enabling disclosure. *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971).

Reconsideration and withdrawal of the rejection is therefore respectfully requested.

D. Second Paragraph

Claims 3-6, 15 and 17 stand rejected as allegedly indefinite. Applicants traverse. However, claim 15 has been canceled, rendering that rejection moot.

Claims 3-6 are rejected for the use of future tense ("will ...."). Applicants traverse, but in order to advance the prosecution, applicants have amended the claims to delete this language.

Claim 17 stands rejected over use of the term "antibody composition that binding to immunologically to RSV." This grammatical error has been corrected by an amendment.

Reconsideration and withdrawal of each of the foregoing amendments is respectfully requested.

III. Rejection Under 35 U.S.C. §103(a)

Claims 1, 3-7, 9, 11 and 13-15 and 18-20 remain rejected under §103(a) as being unpatentable over Maziere in view of Streckert and Mills. Maziere is cited as teaching that lovastatin inhibits the HIV infective cycle in AIDS patients. Streckert is said to teach homology between fusion proteins of HIV and RSV. Mills is cited as teaching ribavirin treatment for RSV. Applicants once again traverse.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. *Manual of Patent Examining Procedure* §2142. See also *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed Cir. 1991) (emphasizing that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must be both found in the prior art, and

not based on appellant's disclosure). As explained below, at least (1) and (2) above are missing from this rejection.

Just as with the previous examiner, the present examiner is improperly attempting to link the lovastatin teachings of Maziere to RSV using the Streckert reference, which is said to teach a common feature between HIV and RSV. The question, however, is ***why***? Why would one choose to select Streckert, which allegedly shows commonality in the fusion proteins of HIV and RSV, and ignore a host of other references that teach ***differences*** between HIV and RSV? For example, it is well known that RSV is a cytoplasmically replicating virus, whereas HIV is a nuclear replicating virus. Does this very significant difference in virus replication not teach away from using the same drug on both viruses? And why select HIV and RSV for comparison? Why not a virus more closely related to RSV?

The answer to all of these questions is quite simple. The examiner is continuing to conduct an improper hindsight reconstruction of the invention using applicants' claims as a road map. The examiner has identified nothing in Maziere to suggest that lovastatin was acting at the level of virus fusion. Such a teaching would be the only way the examiner could then go about selecting Streckert from among the thousands of possible secondary references. In the absence of such a teaching in Maziere (since Mills is silent on lovastatin), it is absolutely clear where the examiner identified the suggestion to combine the primary reference with Streckert – ***applicants' claims*** – and all concerned here know that such a practice is strictly prohibited by controlling case law. "It is difficult but necessary that the decision maker forget what he or she has been taught ... about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." *W.L.*

Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Thus, again, as with all of the previous rejections, the record remains completely devoid of the necessary motivation to combine these references, and hence a *prima facie* case of obviousness hast not been established. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

IV. Conclusion

In light of the foregoing, applicants submit that all of the pending claims are in condition for allowance, and an early notification to that effect is earnestly solicited. A telephone call to the undersigned is invited should there be any questions regarding this paper.

Respectfully submitted,

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